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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,981	06/05/2000	Jeffrey M. MacDonald	113918.201	8826

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/586,981

Applicant(s)

MACDONALD ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-29, drawn to a bioreactor, classified in class 422, subclass 44.
 - II. Claim 31, drawn to a method of manufacture of a bioreactor, classified in class 242, subclass 437.3.
 - III. Claim 34, drawn to an apparatus for assembly of a bioreactor, classified in class 156, subclass 172.
 - IV. Claims 35-37, drawn to a device for maintaining viable eukaryotic cells, classified in class 435, subclass 809.
 - V. Claims 38-44, drawn to a method of treatment of a patient, classified in class 604, subclass 6.09.
 - VI. Claims 45-47, drawn to a method of selecting and controlling a flow rate, classified in class 73, subclass 861.
 - VII. Claim 48, drawn to a microprocessor, classified in class 714.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions Groups I and II are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed may be used to make a conventional hollow-fiber blood oxygenator.

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3. Inventions in Groups I and III are related as product made and apparatus for its manufacture. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, the product may be made by use of a hollow-fiber winding device, and the presence of a vacuum source is not obvious. Further, the apparatus may be used for making any conventional hollow-fiber oxygenator. Still further, the product as claimed may be manufactured by a conventional hollow-fiber winding device.

4. Inventions in Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions consist of a bioreactor and a cell culture apparatus. The bioreactor serves to treat a patient by passing a solution through the hollow fibers of the device for treatment. The cell culture apparatus serves merely to cultivate and aerate living cells for later use in patient treatment.

5. Inventions in Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as

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claimed can be performed by a conventional hollow-fiber oxygenator or other hollow-fiber blood filter.

6. Inventions in Groups I and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the selection of a flow rate has separate utility such as measuring flow through any conduit or hollow-fiber filter. The bioreactor is not disclosed to have any means for selecting or controlling a flow rate therethrough. The measurements of hydraulic pressures to select a flow rate, producing an algorithm for controlling fluid flow, is not exclusive to the determination of a flow rate in a bioreactor. See MPEP § 806.05(d).

7. Inventions in Groups I and VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the microprocessor has separate utility such as use in any device that uses pressure and flow measurements to control a flow through the apparatus, such as any extracorporeal flow device. See MPEP § 806.05(d).

8. Inventions in Groups II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the assembly of a hollow fiber device may be performed by a conventional hollow-fiber winding device, or by hand.

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9. Inventions in Groups II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The method of manufacturing a bioreactor simply provides for the assembly of the bioreactor, and not for the manufacture of a cell culture device. The invention in Group II is a method of manufacture that produces a hollow fiber device, whereas the invention in Group IV is a cell culture device, neither of which performs a function similar to the other.

10. Inventions Groups II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions consist of a method of manufacture and a method of patient treatment. One method produces a hollow-fiber device, and the other method treats the body fluid of a patient, each of which are unrelated functions.

11. Inventions in Groups II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of manufacture and a method of selecting a flow rate that produces an algorithm for controlling fluid flow, which are not performed together, and have different functions within the claimed invention.

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12. Inventions In Groups II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of manufacture and a microprocessor. The method of manufacture produces a hollow fiber device, and is not disclosed as utilizing a microprocessor. The microprocessor may be used to control a variable set of commands.

13. Inventions Groups III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are an apparatus for assembly of a bioreactor, and a device for maintaining the viability of cells. The assembly apparatus is not disclosed as manufacturing a cell culture device. The assembly apparatus produces a hollow fiber device, whereas the cell culture device produces viable cells.

14. Inventions in Groups III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of manufacturing a bioreactor and method of patient treatment. The method of manufacturing a bioreactor produces a hollow fiber device, and the method of treating a patient produces healthy cells.

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15. Inventions in Groups III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, since the method of manufacture of a bioreactor produces a hollow fiber device, and the method of selecting a flow rate that produces an algorithm for controlling fluid flow.

16. Inventions in Groups III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together, as the method of manufacture produces a hollow fiber device, and the microprocessor controls a method of fluid flow through a device.

17. Inventions in Groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell culture device for maintaining viable cells and a method of patient treatment. The cell culture device produces viable cells, and the method of patient treatment produces a processed body fluid product.

18. Inventions Groups IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell culture device that produces viable cells, and a method of selecting a flow rate that produces an algorithm for controlling fluid flow.

19. Inventions Groups IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell culture device that produces viable cells, and a microprocessor that controls a method of fluid flow through a processing device.

20. Inventions in Groups V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of patient treatment that produces a processed body fluid product and a method of selecting a flow rate that produces an algorithm for controlling fluid flow.

21. Inventions in Groups V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of patient treatment that produces a processed body fluid product and a microprocessor that controls a method of fluid flow through a processing device.

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22. Inventions in Groups VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of patient treatment that produces a processed body fluid product and a microprocessor that controls a method of fluid flow through a processing device.

23. This application contains claims directed to the following patentably distinct species of the claimed invention: Claims 1-22, 23-28, and 29, all drawn to bioreactors with similar structures, but different detailed features.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 29 is held to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

24. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.


Ird
July 31, 2002



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